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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,230	08/24/2001	Alan David Wickenden	018512-006610US	5203

20350 7590 04/11/2007
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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/939,230	WICKENDEN ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-57,60-63,65-69 and 83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-57,60-63,65-69 and 83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 45-57, 60-63, 65-69 and 83 are presented for examination.

Applicant's Amendment filed September 25, 2006 has been received and entered into the present application.

Claims 45-57, 60-63, 65-69 and 83 are pending and under examination. Claims 45 and 63 are amended.

Applicant's arguments, filed September 25, 2006, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-57 and 60-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claim 45 has been amended to limit the moiety Ar2 from "aryl, substituted aryl, heteroaryl and substituted heteroaryl" to now read upon the genus of "5-6 membered aromatic ring containing 1-3 heteroatoms wherein said heteroatoms are each independently selected from the group consisting of N, O and S".

Applicant directs the Examiner to the description presented at page 19, lines 17-19 and the various structures presented at Figure 7 of the specification in support of this newly amended claim.

While such portions of the accompanying originally filed specification have been considered, Applicant has failed to provide adequate written support for the newly claimed limitation directed to embodiments wherein Ar2 is, specifically, a 5-6 membered aromatic ring containing 1-3 heteroatoms wherein said heteroatoms are each independently selected from the group consisting of N, O and S.

Applicant's disclosure presented at page 19, lines 17-19 diffusely discusses possible aryl groups that may be used within the context of the instant invention, but fails to provide specific direction out of the breadth of options to specifically narrow the genus of Ar2 to "5-6 membered aromatic rings containing 1-3 heteroatoms wherein said heteroatoms are each independently selected from the group consisting of N, O and S." Furthermore, though the various structures presented at Figure 7 have been fully studied and considered, it remains that these structures only support the use of the a 6 membered aromatic group with 1-N substitution. This single heteroatom substitution in the 6-membered aromatic ring is further supported by disclosure presented in the specification bridging pages 5-6.

Regarding Applicant's newly added limitation directed to embodiments of the claimed genus of compounds wherein the aryl moiety Ar2 is a "5-6 membered aromatic ring containing 1-3 heteroatoms wherein said heteroatoms are each independently selected from the group consisting of N, O and S", the specification, drawings and claims as originally filed fail to provide adequate written support to now narrow the genus of Ar2 to, specifically, only 5-6 membered aromatic rings containing 1-3 heteroatoms, wherein the heteroatoms may be nitrogen, oxygen or sulfur. Though Applicant discloses various aryl or heteroaryl moieties that may be used in the generic formula for Ar2, it remains that the disclosure as originally filed fails to provide adequate written support for the substitution of Ar2 with, in particular, the much narrower genus of only 5-6 membered aromatic rings containing 1-3 heteroatoms, wherein the heteroatoms may be nitrogen, oxygen or sulfur. Accordingly, the disclosure of generic aryl or heteroaryl

groups does not provide sufficient direction to one skilled in the art at the time of the present invention to specifically select the newly claimed aryl moieties and, therefore, the addition of the limitation to the claims represents a narrowing of the subject matter disclosed in the specification, claims, and drawings as originally filed that does not have adequate written support to show that Applicant was in possession of such a narrow concept at the time of the instant invention.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of embodiments of the claimed generic formula wherein Ar2 is, specifically, a 5-6 membered aromatic ring containing 1-3 heteroatoms wherein said heteroatoms are each independently selected from the group consisting of N, O and S.

Accordingly, for these reasons, claims 45-57 and 60-63 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-57 and 60-63 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of arylamide containing compounds shown in Figure 7 for the treatment of anxiety, does not reasonably provide enablement for the various other compounds that are functionally described as compounds that increase ion flow through KCNQ potassium channels (i.e., the full breadth of compounds claimed in the generic formula of claim 45), for

the reasons of record set forth at pages 5-10 of the previous Office Action dated March 21, 2006, of which said reasons are herein incorporated by reference.

Applicant again traverses the instant rejection, stating that only routine experimentation is required to practice the invention set forth in amended claim 45 and relies upon the fact that the specification sets forth a number of simple assays to identify KCNQ channel openers, either *in vivo* or *in vitro*, such as, e.g., high throughput screening methods, chemical libraries, systematic screening via robotic automation, voltage clamps, patch clamps, radioisotope labeling, etc. Applicant further relies upon the previously submitted Declaration of Dr. Douglas Krafte (previously addressed by the Examiner in the prior Office Action) as evidence that the Geller assay is an art-accepted model for testing anxiety compounds and that Dr. Krafte was not aware of any reasoning or evidence as to why one skilled in the art would doubt the usefulness of the disclosed assay. Applicant references the *in vivo* working example of "a KCNQ 2/3 channel opener" administered in accordance with the Geller model assay to show anxiolytic activity (see Example 6) and states that the Examiner has presented no evidence or reasoning as to why one skilled in the art would conclude that a KCNQ channel opener would not work as intended in the claimed methods.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

The focus of Applicant's traversal appears to be based upon the fact that the disclosure provides sufficient guidance or direction to determine which compounds would be operable to function as KCNQ channel openers and which compounds would be inoperable with no more than routine experimentation. However, the fact remains that Applicant has not provided the skilled artisan with sufficient direction as to how to use the present invention commensurate in scope with the presently claimed subject matter because the claims encompass such a breadth of compounds with significant and substantial variation in chemical structure and, therefore, functional variation, that the skilled artisan would be required to

undertake extensive hit or miss testing practices to determine which compounds out of the thousands, if not millions, presently claimed actually functioned to operate as KCNQ channel openers. As taught by the MPEP at §2164.08(b), "The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling). Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable."

Applicant's claims encompass generic compounds of at least the basic structure of instant claim 45, but allow for thousands, if not millions, of permutations of this physical structure due to the number of possible moieties that may be attached to, or present in, this basic structure. For example, the aryl moieties Ar1 and/or Ar2 range from unsubstituted carbocylic aromatic ring structures to substituted furanyl rings and X may be oxygen, sulfur or NR1, wherein R1 may then range from various substituted or unsubstituted alkyl structures to substituted heteroaryl structures to other various highly electron withdrawing substituents, such as, e.g., carbonyl, cyanide, hydroxyl, carbamoyl, sulfamoyl, etc., which would indisputably alter the reactivity of the molecule as a whole. Such substitutions give rise to an enormous number of compounds that are substantially different in physical and chemical structure such that the efficacy demonstrated with a single species (i.e., the compound employed in Example 6) or the various structures presented in Figure 7, which, importantly, are comprised of a core structure wherein X is always oxygen and Ar2 is always a nitrogen heterocycle with one nitrogen substitution, would not necessarily be representative of such a vast and variable genus of compounds, depending on the substitution present in the molecule. One of skill in the art would have reasonably expected significant

variation in the activity of the compounds to function as KCNQ channel openers such that, in order to determine the full scope of compounds that might be employed in the instantly claimed method, the skilled artisan would have been required to undertake an undue burden of experimentation to make such a determination.

It was known in the art at the time of the present invention that even compounds that share similar structural properties could not be guaranteed to have the same level of activity. Such is the unpredictable nature of the pharmaceutical arts, since two-dimensional structural organic formulas are poor means of representing the physical, chemical or biologic properties of a molecule. Structural formulas merely depict the way the various atoms are strung together to form what is known as a *molecule*, but are not necessarily predictive of pharmacologic activity. Factors that strongly include the pharmacologic activity of a drug include, but are not limited to, molecular size, shape, ionization, charge distribution, solubility, interatomic distance, geometric and stereochemical configurations, and the rigidity or flexibility of the molecule.

This well-recognized unpredictability in the art must be taken into consideration when determining whether a disclosure fails to provide sufficient enabling direction for the claimed subject matter. As directed by the MPEP, the amount of guidance required to be present in the specification as originally filed is directly proportional to the amount of knowledge in the art as well as the unpredictability in the art. In other words, if little or nothing is known in the prior art about an aspect of the claimed invention and the art is unpredictable, the specification needs more detail and guidance as to how to use the invention in order to be enabling. Please reference *In re Fisher*, 417 F.2d 833, 839, 166 USPQ 18, 23 (CCPA 1970) and *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004).

It is well settled in patent law that in cases involving chemicals and chemical compounds, which differ radically in their properties, it must appear in an Applicant's specification either by the enumeration

of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result. Please reference *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940). Though Applicant's exemplification of the compound used in Example 6 and the structures elucidated in Figure 7 have been noted, these examples are not sufficiently representative of the thousands, if not millions, of compounds presently claimed in instant claim 45, absent any evidence or reasoning by Applicant addressing the unpredictability in the pharmaceutical and medical arts and how these single examples are representative of the claimed genus as a whole. While the lack of multiple working embodiments cannot be the *sole* factor in determining enablement, the absence of substantial evidence commensurate in scope with the breadth of the presently claimed subject matter, in light of the unpredictable nature of the art and the limited direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole.

Applicant urges the working example of the Geller assay using a compound with "selective KCNQ2/3 channel activity", but, importantly, fails to ever state the identity of the compound used. In view of this lack of identification of the compound, Applicant's reliance upon this working example as providing enabling direction and guidance for the full scope of the claimed invention is not persuasive in establishing error in the propriety of the instant rejection. Absent any identification of the compound, Applicant's argument that one would be able to extrapolate the results seen with this KCNQ2/3 channel opener to the breadth of compounds now claimed is not persuasive, particularly because the notable absence of the physical structure of the tested compound precludes the use of such a structure to identify other compounds with a common structural element to that tested as being reasonably expected to have similar KCNQ channel opening activity. Accordingly, though the working example has been noted, it has absolutely no influence on the allegation that the claimed subject matter is, in fact, enabled for the full scope of the claims.

It is noted that Applicant is not required to enable each an every single embodiment encompassed by the claims. While the scope of the required enablement varies inversely with the degree of unpredictability involved, even in the unpredictable arts, such as pharmaceuticals and medicine, a disclosure of every operable species is not required. However, while a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, [please see *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971)], in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. Please reference *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. Please reference *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species what other species will work. Please see MPEP §2164.03. In the absence of additional disclosure, the skilled artisan would be required to perform an undue level of experimentation in order to determine these other species that would be capable of performing the claimed method.

Applicant again relies upon the Declaration of Dr. Douglas Krafte, which was previously addressed by the preceding Examiner in the prior Office Action of March 21, 2006, in support of the assertion that the Geller assay is an art-accepted model for testing anxiety compounds and that he is not aware of any reasoning or evidence as to why one skilled in the art would doubt the usefulness of the disclosed assay. However, neither the acceptability of the Geller assay in determining the anxiolytic efficacy of a compound nor the "usefulness" of the disclosed assays is disputed. Rather, the issue at hand is that one of skill in the art would be required to undertake a burden of undue experimentation to use

such disclosed assays to determine the scope of compounds capable of functioning as KCNQ potassium channel openers because it is not plainly apparent or obvious from the disclosure what other species aside from, e.g., those in Figure 7, have the claimed activity in functioning as KCNQ channel openers and, thus, would be amenable for use in the present invention.

Applicant is reminded once again that the basis for the present rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure and remarks that experimentation in this particular art is not uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*." (emphasis added) Insofar as Applicant presents no evidence to the contrary in support of the fact that *undue* experimentation would be required, the claims remains properly rejected as failing to comply with the enablement requirement of 35 U.S.C. 112, first paragraph.

For these reasons, and those previously set forth at pages 5-10 of the previous Office Action dated March 21, 2006, rejection of claims 45-57 and 60-63 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-57, 60-63, 65-69 and 83 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 22 of U.S. Patent No. 6,459,550, for the reasons of record set forth at page 14 of the previous Office Action dated March 21, 2006, of which said reasons are herein incorporated by reference.

Applicants respectfully note that a terminal disclaimer will be filed in view of any outstanding obviousness-type double patenting rejections upon allowance of the claims.

In view of the fact that the instant claims are not in condition for allowance at the present time, and further in view of the fact that Applicant presents no arguments or Terminal Disclaimers regarding the obviousness-type double patenting rejection of record, the rejections remain proper for the reasons set forth at page 14 of the previous Office Action and is, therefore, properly **maintained**.

Conclusion

The newly cited art of record is considered pertinent to Applicant's disclosure insofar as it shows the general state of the pharmaceutical art at the time of the invention but is not relied upon as support for any of the rejections set forth and maintain herein this Office Action. Please reference Remington's Pharmaceutical Sciences (Sixteenth Edition, Chapter 27: Structure-Activity Relationship and Drug Design, 1980; pages 420-435).

Rejection of claims 45-57, 60-63, 65-69 and 83 remains proper and is **maintained**.

No claims of the instant application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

March 30, 2007

ARDIN H. MARSCHEL 4/1/07
SUPERVISORY PATENT EXAMINER